Please add the following new claims:

16. (new) The tissue rivet of claim 9 in which said flexible projections are positioned in a radially staggered configuration along said shaft.

17. (new) The tissue rivet of claim 16 in which no more than two apexes of said flexible projections are in one plane perpendicular to the longitudinal axis of said shaft at any point along said shaft, whereby the resistance at the point of insertion in the tissue is kept at a minimum to facilitate the insertion of said rivet through an opening in the tissue in which said rivet is inserted.

18. (new) The tissue rivet of claim 9 in which said flexible member has a greater surface area to mass ratio than said hollow shaft for permitting a higher absorption rate of said bioabsorbable material of said flexible member.

REMARKS

Claim 14 has been cancelled from the Application. The language of claim 9 has been amended to delete the limitation that the projections are disposed along substantially the entire length of the shaft. The language of claim 9 has also been amended to replace "individual" with "separate", to replace "absorbable" with "bioabsorbable" and to recite the spacing of the projections with respect to each other as being at a distance that is less than the height of a single projection. Support for this amendment is found in Figures 1 and 4-8 of the Application. No new matter has been added. The language of claim 11 has been amended such that preamble now more correctly recites that the claim is a combination claim. It is believed that as now amended, the objection to the claims and the specification under 35 U.S.C. § 112 have been overcome.

New claim 16 has been added drawn dependent from claim 9 to recite the tissue rivet of the claimed invention as having flexible projections positioned in a radially staggered configuration along the shaft. New claim 17 has been added drawn dependent from claim 16 to recite the tissue rivet of the claimed

invention in which no more than two apexes of the flexible projections are in one plane perpendicular to the longitudinal axis of the shaft at any point along the shaft, whereby the resistance at the point of insertion in the tissue is kept at a minimum to facilitate the insertion of the rivet through an opening in the tissue in which the rivet is inserted. In this manner the tissue is not overstretched and damage to the tissue is kept at a minimum. Support for this amendment is found in Figure 1 of the Original Application. No new matter has been added.

New claim 18 drawn dependent from claim 9 has been added to recite the flexible member as having a greater surface area to mass ratio than the shaft. As can be seen in Figures 1 and 4 of the Original Application, the flexible member (disc 18) comprises almost entirely of a large exposed surface area that is in contact with the tissue and a relatively smaller interior portion that is not exposed to the tissue. This structure permits the flexible member of the rivet of the claimed invention to have a higher absorption rate of the bioabsorbable material of which the flexible member is made. This is an important advantage over the structure of the Bays et al. rivet which has a head 15 having a greater mass, and lower surface area to mass ratio than the shaft 14 such that a lower rate of absorption of the head 15 relative to the shaft 14 is possible. With the Bays et al. rivet, the lower rate of absorption of the head 15 may cause the head 15 to become dissociated from the shaft 14 and become lodged in the joint of the knee causing damage to the delicate tissues of the articular joint. Similarly, the head of the Chisholm et al. device is not flexible to be capable of deforming so as to conform to the surface of the tissue in which said rivet is inserted and has a greater mass to surface area ratio.

In the claimed invention, the flexible member of the rivet has a higher absorption rate than the hollow shaft, such that when resorption occurs, the flexible member would resorb

prior to the resorption of the hollow shaft eliminating the possibility that the flexible member would become dissociated from the hollow shaft prior to the completion of the resorption process.

The language of claim 9 has been further amended to recite that the flexible member of the rivet is flexible so as to be able to deform and conform to the surface of the tissue in which the rivet is inserted as shown in Figure 4 of the Application. Such structure is not taught by Bays et al. The larger T-shaped head of the rivet of Bays et al. is not disclosed as being flexible so as to be able to deform and conform to the surface of the tissue, but forms a sharp angle with the tissue, thereby creating a projection which could result in irritation in the tissues of the joint in which the tissues are being repaired. (See Col. 4, lines 20-28.)

The language of claim 9 has further been amended to recite the flexible projection as being separate from one another. This spacing in combination with the flexible structure of the projections allows the separate projections of the claimed invention to flex towards the shaft when being inserted in the tissue. Further, the "close spacing" of the flexible projection has been more clearly defined as each of the flexible projections having an apex at a maximum height from the shaft so that the apex of consecutive separate flexible projections are spaced at a distance that is less than the maximum height of a single projection. It is believed that the rejection under 35 U.S.C. § 112, first paragraph has been overcome. Support for this amendment is found in Figures 1 and 4-8 of the Application. No new matter has been added.

In contrast, Bays et al. teaches barbs that are not flexible since they are positioned adjacent to one another along the shaft as shown in Figures 2, 3, 5 and 6 and are incapable of flexing toward the shaft when inserted in tissue. As there is no space between the barbs of Bays et al., the barbs have no room to flex toward the shaft because the next in line barb will prevent

the barb from flexing. Further, as can be seen in Figures 3 and 7 of Bays et al., showing a cross sectional view of the barbs, each of the barbs have a solid, wide attachment point along the longitudinal axis of the shaft. The wide attachment point of each barb in Bays et al. does not permit the projection of Bays et al. to flex so that they may be pushed through an opening that is smaller than the largest outside dimension of the projections. Instead, the barbs of Bays et al. have a tapered surface 18 "to facilitate the passage of the shaft portion 14 of the tack member 10 through cartilaginous or other tissue when the tack is moved forwardly (i.e. in the direction along the axis of the shaft position 14 and bone 13 from proximal end 11 toward distal end 12.)" (Col. 4, lines 37-42.)

The Bays et al. rivet is held in place by the projections, particularly the front projection which creates a hole in the tissue that is greater than the outside diameter of the remaining projections. The entire Bays et al. rivet has the potential of retreating out of the opening after its insertion. It is possible that the Bays et al. rivet would work to fix soft tissue to bone, but it will not work to fix soft tissue to soft tissue as the barbs would core out a path through the soft tissue or stretch the soft tissue to the same diameter of the barbs such that there would be tissue left for the Bays et al. rivet to engage. In contrast, the projections of the rivet of the claimed invention do not increase the size of the opening in the tissue.

In further contradistinction, as recited in claim 9, the projections of the claimed invention are separate, flexible projections, flexing toward the shaft as they are pushed through a smaller opening in the tissue than the largest outside dimensions of the projections. In this manner, no path is cored out through soft tissue and the soft tissue is only minimally stretched. This is not taught, disclosed or suggested by Bays et al.

Furthermore, Applicant respectfully disagrees with the Examiner's submission that the Bays et al. projections or barbs

are flexible based on the ground that disclosed material is disclosed as being "semi-rigid". As discussed above, the barbs of Bays et al. are not capable of flexing toward the shaft. The disclosure in Bays et al. cited by the Examiner that the barbs could be "semi-rigid" does not automatically suggest that the barbs would be flexible towards the shaft. "Semi-rigid" is a relative term such that the Bays et al. barbs could be "semi-rigid" compared to metal, but rigid compared to body tissue. The disclosure and none of the Figures of Bays et al. teach, disclose or suggest any use of the Bays et al. device that would permit the barbs to be flexible towards the shaft. The inflexible nature of the barbs of Bays et al. is most apparent in Figures 3 and 7 of showing a cross section of the barbs.

Moreover, there is no suggestion in Chisholm et al, that the projections of Chisholm et al. could be incorporated in the Bays et al. to form a medical rivet device. The Bays et al. device is a surgical rivet and specifically calls for rigid projections designed for a specific purpose, namely for meniscal repair. The Chisholm device is for a standard rivet that would be used in non-medical applications, such as in an automobile for fastening decorative trim to an automobile door interior. (col. 2, lines 25-26.) The Chisholm et al. device is not bioabsorbable and is not suitable for medical use in the human body. There is no teaching, disclosure or suggestion that the Chisholm et al. device could be used as a medical device to fasten tissue.

Even if the Chisholm et al. were to be reduced in size to be appropriately small for use in meniscal repair, it would not be insertable as it structure would be too weak due to its disproportionately large sized head relative to the shaft portion and barbs. There is no teaching, disclosure or suggestion in Chisholm et al, that if the Chisholm et al. device were to reduced in size, that the projections would be flexible toward the shaft when inserted in bodily tissue. In addition, the Chisholm et al. device does not have a hollow shaft to allow for the use of a driving means that is inserted in the hollow shaft

for the insertion of the Chisholm et al. device.

Further, the automotive rivet of Chisholm et al. is non-analogous art and certainly would serve no purpose in meniscal repair. As stated In Re Clay, 23 U.S.P.Q. 2d 1058 (Fed. Cir. 1992), the criteria for determining whether prior art is analogous has been developed over a period of years and includes the following elements:

> "1. Whether the art is from the same field of endeavor, regardless of the problem addressed, and,
> 2. If the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved."

The Court of Appeals in this case cited In Re Deminski, 796 F.2d 436, 432, 230 U.S.P.Q. 313, 315 and In Re Wood, 599 F.2d 1032, 1036, 202 U.S.P.Q. 171, 174.

Taking these elements into account, one must first look whether the art is from the same field of endeavor. It is respectfully noted, that the Chisholm et al. patent is directed to an automotive rivet which is not from the same field of endeavor as the medical rivet of the present invention.

With respect to the question of whether the "reference still is reasonably pertinent to the particular problem with which the inventor is involved", in fact the inventor of the present invention is not involved with automotive rivets for securing the trim to the interior of an automotive door, but rather is involved with the repair of the meniscus of a human face.

In an opposite vein, the question is whether a person using the automotive rivet as provided by Chisholm et al. would think of the automotive rivet as being useful for repairing the

meniscus of a human knee. The Chisolm et al. rivet is for inert material wherein tissue viability is not a concern because it does not matter whether the inert material is stretched apart. In contrast, it is essential to tissue viability that the tissue not be overstretched. It is the flexible projections of the claimed invention which deform to limit the stretching of the tissue through which the rivet of the claimed invention is being inserted. Thus, injury to the tissue is kept at a minimum by the claimed invention. It is believed that the fields of Chisholm et al. and the field of the present invention are substantially remote from each other and that there would not be any overlap or thinking in the mind of a reasonable person that such would be considered analogous in the meaning of the Patent Statute.

For the reasons discussed above, it is not believed that the Chisholm et al. patent can reasonably be classified as "analogous art". Accordingly, it is believed that claim 9, as amended, presents novel and non obvious subject matter to overcome the rejections under 35 U.S.C. § 102(e) and § 103. As claims 11, 12, 15, and new claims 16 and 17 are drawn dependent from claim 9, they are also believed to be allowable for the same reasons set forth above, in the discussion of claim 9. In addition, claims 11 and 12 include a driving means tip for a smooth transition from the tip of the driving means and the head of the rivet. The Examiner does not cite any portion of Bays et al. that teaches discloses or suggests such a feature in the rejection.

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For the foregoing reasons, it is believed that all of the above claims, as amended, are allowable over the prior art of record and that the Application is now in condition for allowance. A Notice of Allowance is requested.

Should the Examiner have any further questions, please contact the undersigned directly.

Respectfully submitted,

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